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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/756,188      | 01/12/2004  | Brian P. Brockway    | 020819-000120US     | 2296             |

20350 7590 04/19/2007  
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| EXAMINER |
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SCHAETZLE, KENNEDY

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3766

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 04/19/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/756,188

Applicant(s)

BROCKWAY ET AL.

Examiner

Kennedy Schaetzle

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,8 and 14-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,8 and 14-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Objections*

1. Claims 16 and 17 are objected to because of the following informalities: there is no reference frame given for the distances recited (e.g., the distance recitations could broadly refer to the distance in a radial direction from the wall of the vessel adjacent to the distal end, or an axial direction from the site of insertion into the vessel). The examiner assumes it was the applicant's intent to claim the later, but appropriate correction is required in order to eliminate any vagueness.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 8, 14 and 29 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sheldon et al. (Pat. No. 6,937,899).

### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 15-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al. in view of Brockway et al. (Pat. No. 4,846,191).

Sheldon et al. do not discuss particulars associated with the detection of vascular blood pressure. Brockway et al., however, disclose such details with an implantable sensor that can be used in any situation requiring an accurate, long-term measure of blood pressure and/or accurate control of therapeutical devices (note col. 3, lines 27-36, col. 4, lines 28-38). The method of Sheldon et al. requires exactly such a sensor since it is required to provide accurate, reliable, feedback data of vascular blood pressure for controlling therapy application in a chronically implanted system. Those of ordinary skill in the art given the sensor requirements set forth by Sheldon et al. and the advantages of a candidate sensor meeting the requirements as disclosed by Brockway et al., would have clearly seen the obviousness of employing the sensor of Brockway et al. into the system and method of Sheldon et al..

Regarding claims 16 and 17, while Brockway et al. does not explicitly refer to the distances associated with the insertion of the transmission catheter into the vascular lumen, since the conveyed fluid pressure only depends on the pressure acting at the very distal tip of the transmission catheter, it is only the very distal tip (i.e., that region containing the barrier) that need be inserted in order to expose the sensor to the forces of pressure. Brockway et al., in fact, show in Fig. 1 a sensor with just the tip inserted into the vasculature. Those of ordinary skill in the medical arts recognizing that only the tip of the sensor need be inserted, and given the general knowledge that the greater the surface area of a foreign body inserted into the blood stream, the greater the chance that blood will clot along the exposed surface, as well as the general desire to ensure vessel patency to the flow of blood, would have seen the obviousness of limiting the extent of the catheter into the blood vessel to prevent any possible and unnecessary risk to the patient. Furthermore as discussed above in the objection to the language of claims 16 and 17, one can consider the 5 to 10 mm distance to relate to the distance of the distal end from the wall of the vessel in a radial direction. Blood vessels of diameters in this range would inherently limit the extent of the distal end insertion in the radial direction. In addition, the distances involved with distal end insertion may depend on the size of the subject within which the device is intended to be located and thus considered a matter of obvious design.

Art Unit: 3766

Regarding claim 26, the cross-linked, silicone-based gel barrier of Brockway et al. is considered to be a polymeric membrane (attention is invited to Brockway et al. '366 which refers to the same gel barrier as both a plug and a membrane). The applicant further has not defined the term "membrane" with any specificity to distinguish over the thin, pliable layer barrier of Brockway et al..

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJS  
April 10, 2007



KENNEDY SCHAETZLE  
PRIMARY EXAMINER